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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,574	02/08/2002	Lone Jeppesen	5698.210-US	2406

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EXAMINER	
TRUONG, TAMTHOM NGO	
ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,574	JEPPESEN ET AL.	
	Examiner	Art Unit	
	Tamthom N. Truong	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7,17,45-47,54 and 55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,2,7,17,45-47 and 55* is/are allowed.

6)☒ Claim(s) *54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

FINAL ACTION

Applicant's amendment has been fully considered. In view of the support on pages 6 and 8 for "C_{1-7}alkyl, C_{2-7}alkenyl, C_{2-7}alkynyl, C_{1-7}alkoxy", the previous rejection of new matter is withdrawn for claims 1, 2, 7, 17, 46, 47, 53-55. However, the amended claim 54 has not overcome the enablement rejection. Therefore, said rejection is maintained for claim 54.

With claims 3-6, 8-16, 18-44, 48-53, and 56-60 cancelled, claims 1, 2, 7, 17, 45-47, 54, 55 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. **Scope of Enablement:** Claim 54 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of diabetes or obesity, does not reasonably provide enablement for the treatment of other conditions mediated by the Peroxisome Proliferator-Activated Receptors (PPAR). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

(1) The breadth of the claims;

(2) The amount of direction or guidance presented;

(3) The state of the prior art;

(4) The relative skill of those in the art;

(5) The predictability or unpredictability of the art;

(6) The quantity of experimentation necessary;

[See ***Ex parte Forman***, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also ***In re Wands***, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

a. **The breadth of the claims:** Claim 54 recites a method "*for the treatment of conditions mediated by the Peroxisome Proliferator-Activated Receptors (PPAR)*", which covers an array of diseases such as: type 2 diabetes; dyslipidemia; disorders related to Syndrome X such as hypertension, obesity, insulin resistance, hyperglycemia, atherosclerosis, hyperlipidemia, coronary artery disease, other cardiovascular disorders; glomerulonephritis, glomerulosclerosis, nephritic syndrome, hypertensive nephrosclerosis, psoriasis, polycystic ovarian syndrome (PCOS), osteoporosis, etc. Many of said diseases relate to factors other than lipid and sugar. For examples, hypertension as well as other cardiovascular disorders are complicated, an involved other factors such as sodium, potassium, calcium channel, elasticity of the blood vessels, etc., and not just lipid and sugar. Similarly, other disorders such as glomerulonephritis, psoriasis, PCOS, osteoporosis could be drug-induced, hormone dependent, genetic makeup or nutrition. Since PPAR helps reducing free fatty acids, which in turn helping the body burn more glucose, its role in treating diabetes and obesity is more apparent than treating other disorders.

b. **The amount of direction or guidance presented:** The specification only outline the *in-vitro* assays, but does not provide IC_{50} values for the claimed compounds. Thus, for a large genus of compounds claimed herein, one skilled in the art would have to carry out more than routine experimentation to find out which of the claimed compounds could actually exert an effect on PPAR. Also, there is no evidence in the specification to allow one skilled in the art to extend the activity of the claimed compounds to the treatment of hypertension, other cardiovascular disorders, disorders related to Syndrome X, various kidney diseases, psoriasis, PCOS, and osteoporosis.

c. **The state of the prior art:** Currently, the practice of medicine does not use an antidiabetic drug to treat hypertension, or other cardiovascular disorders, simply because blood pressure is a dynamic disorder that cannot simply be treated by lowering glucose. Although agents lowering lipid (as an adjuvant agent) helps in preventing artherosclerosis, they have never been used as the main agent for treating hypertension, cardiovascular disorders, psoriasis, PCOS, and osteoporosis, etc. which are allegedly related to PPAR.

Thus, with the unpredictable nature of the art, and the limited teaching, it would take undue experimentation for the skilled clinician to apply the claimed compounds in the treatment of the myriad of diseases that are allegedly related to PPAR.

Allowable Subject Matter

2. Claims 1, 2, 7, 17, 45-47, and, 55 are allowed since the art of record do not teach a tricyclic system as claimed herein.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (~10 am ~ 6:30 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached at 571-272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting SPE of 1624, at 571-272-0661.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

T. Truong
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April 28, 2004

RICHARD L. RAYMOND
PRIMARY EXAMINER
ART UNIT 1624